

**REMARKS**

**Introductory Comments:**

Claims 1, 3, 4, 13, 16-20 and 28-50 were examined in the Office Action under reply and stand rejected under (1) the judicially created doctrine of obviousness-type double patenting (claims 1, 3, 16-18, 28-32, 34-36, 38 and 45-48); and (2) 35 U.S.C. §112, second paragraph (claims 1, 3, 4, 13, 16-20 and 28-50). These rejections are respectfully traversed as discussed more fully below.

Applicants note with appreciation the withdrawal of the previous rejection of claims 4, 13, 19, 20, 33, 37, 39-44, 49 and 50 under the judicially created doctrine of obviousness-type double patenting, as well as the previous objection of claims 19, 39, 41 and 44.

**The Double Patenting Rejection:**

Claims 1, 3, 16-18, 28-32, 34-36, 38 and 45-48 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-48 of U.S. Patent No. 6,767,892 (USSN 09/188,051). Applicants continue to traverse this rejection for reasons of record. In particular, as previously explained to the Examiner, claim 1 of the '892 patent recites a pH of 5.5 or greater while the present claims recite a pH of 5.0 or greater. Additionally, claim 1 of the '892 patent recites a temperature of about 4 degrees C and the presence of a guanidinium solubilizing compound, while the present claims do not include a temperature limitation or the presence of such a compound. Finally, and importantly, claim 1 of the '892 patent recites an IGF concentration of about 12 mg/ml to about 200 mg/ml when the composition is at a temperature of about 4 degrees C, while the present claims recite a concentration of about 250 mg/ml.

Nevertheless, in an effort to advance prosecution, applicants will consider the propriety of filing a Terminal Disclaimer when subject matter is considered allowable in this application.

Rejection Under 35 U.S.C. §112, Second Paragraph:

Claims 1, 3, 4, 13, 16-20 and 28-50 were rejected under 35 U.S.C. §112, second paragraph as indefinite. The Office argues the use of the term “low salt-containing” renders the claims indefinite. Applicants traverse the rejection.

In particular, the same rejection of the term “low salt-containing” was made and subsequently withdrawn by the previous Examiner. See, e.g., the Office Actions dated April 21, 2001 and May 10, 2001, and the responses dated November 15, 2000 and October 10, 2001. The application was allowed on November 20, 2001 with the terminology “low salt-containing” in the claims. Applicants chose to file a CPA because they were seeking reconsideration of a Petition to correct the filing date of the application. Accordingly, the same rejection has been previously presented, argued and overcome by applicants.

Applicants remind the Examiner that it is contrary to basic fairness and public policy for the Office to reintroduce rejections that have previously been withdrawn. MPEP 706.04 states:

Full faith and credit should be given to the search and action of a previous examiner unless there is a clear error in the previous action or knowledge of other prior art. In general, an examiner should not take an entirely new approach or attempt to reorient the point of view of a previous examiner, or make a new search in the mere hope of finding something.

Since the rejection has already been overcome, reinstatement of the rejection is improper and for this reason alone, then, the rejection should be withdrawn. Nevertheless, applicants will reiterate the previous arguments presented regarding the terminology “low salt-containing.”

The second paragraph of 35 U.S.C. §112 requires that an applicant set out and circumscribe a particular subject area with a **reasonable** degree of precision such that the metes and bounds of the invention are set forth. *Ex parte Head*, 214 USPQ 551 (PTO Bd. App., 1981). The Supreme Court has indicated that the primary purpose of claim language is to give “fair” notice of what would constitute the infringement of a claim. See *United Carbon Co. v. Binny & Smith Co.*, 55 USPQ 381 (1942). In other words, the basic purpose of 35 U.S.C. §112, second paragraph is to require a claim reasonably apprise those skilled in the art of the scope of the invention defined by that claim and give fair notice as to what constitutes infringement of the claim. See *Antonius v. Pro Group Inc.*, 217 USPQ 875, 877 (6<sup>th</sup> Cir. 1983). Moreover, MPEP §2173.05(b) discusses the use of the relative terminology in the claims. As explained therein, the

use of relative terms does not automatically render a claim indefinite. Instead, “[a]cceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification.”

As recognized by the Office, a “low salt-containing” composition as recited in the claims is defined on page 4, lines 11-13 of the specification as a composition with an amount of salt that is insufficient to cause precipitation of the protein. Applicants further provide experimental details in Example 5 on page 23 for preparing salt-containing compositions with precipitated forms of IGF, as well as a test for distinguishing a “low salt-containing” composition of the present invention from a salt-containing composition. Further, the use of the term should be determined in the context in which the term is utilized. In the context of the rejected claims, the term defines aqueous compositions that are (a) low salt-containing; (b) biologically active; and (c) contain specified high concentrations of the biologically active polypeptides. Based on the description provided in the specification and the context in which it is used in the claims, applicants submit that one of skill in the art could readily determine the meaning of “low salt-containing” such that the metes and bounds of the claims would be understood by one of skill in the art. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

**CONCLUSION**


Applicants respectfully submit that the claims define a patentable invention. Accordingly, a Notice of Allowance is believed in order and an early notification to that effect would be appreciated.

Please direct all further communications in this application to:

T. Helen Payne, Esq.  
Chiron Corporation  
Intellectual Property – R440  
P.O. Box 8097  
Emeryville, CA 94662-8097  
Telephone: (510) 923-3004  
Facsimile: (510) 655-3542.

Respectfully submitted,

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By:   
Roberta L. Robins  
Registration No. 33,208  
Attorney for Applicant

Chiron Corporation  
Intellectual Property – R440  
P.O. Box 8097  
Emeryville, CA 94662-8097